3. Avafortan Tablets	M/s. Khandelwal Labs., Bombay. M/s. IDPL, Hyderabad.
4. Spasmizol Tablets & drops	
4. *Analgin Plus Paracetamol:*	
(a) Promolgin Tablets (b) Ultragin Tablets (c) Zimalgin-A Tablets (d) Adol Tablets (e) Delagin Tablets	M/s. Uniloid, Hyderabad. M/s. Manners, Bombay. M/s. Pallis, Bombay. M/s. Acila Pharma, Calcutta. M/s. Pharmed, Bombay.
5. *Paracetamol Plus OxyphenbutaJone Plus Propoxyphene:*	
(a) Butaproxyvon Capsules (b) Combigesic Capsules (c) Parvon Forte Capsules (d) Betaflam Tablets	M/s. Wockhardt, Bombay. M/s. Uniloids, Hyderabad. M/s. Jagson Pal, Delhi. M/s. Vilco, Bombay.
6. *Analgin Plus Oxyphenbutazone*:	
1. Oxalgin Tablets 2. Kilpane Tablets 3. Algesin-D Tablets 4. Largesic Tablets 5. Ganrilon Tablets	M/s. Cadila, Ahmedabad. M/s Biddle Sawyer, Bombay M/s. Alemic, Baroda. M/s Lark Labes, New Delhi M/s. S. G. Pharmaceutical, Bombay.

Marketing permission for combination of drugs

1492. SHRI RAJNI RANJAN SAHU: Will the Minister of HEALTH AND FAMILY WELFARE be pleased to refer to the answer to Unstarred Question 208 given in Rajya Sabha on 7th May, 1986 and state;

(a) whsther it is a fact that state Drug Control Authorities have cleared combination of diugs without clinical trials even after the leceipt of 1985 guidelines;

(b) if so, details of each combination of drugs cleared along with composition of each;

(c) on what basis each combination was allowed and

(d) what are contra-indication and side effects of each combination?

THE MINISTER OF STATE IN THE DEPARTMENT OF HEALTH IN THE MINISTRY OF HEALTH AND FAMILY WELFARE (KUMARI SAROJ KHAPARDE): (a) to (d) This Ministry has HD information whether the State Drug Control Authorities have cleared combinations «f drugs without clinical trials even after the receipt of the guidelines 1985 circulated by the Drugs Controller (India) to all the State Drug$_s$ Control Authorities

Vaccine and sera

1493. SHRI RAINI RANJAN SAHU: Will the Minister of HEALTH AND FAMILY WELFARE be pleased to refer to the answer to Starred Question No. 219 given in the Rajya Sabha on 7 May,
1986 and state:

(a) whether it is a fact that sera and vaccine are released for human consump tion in routine;

(b) what are the names of vaccines and sera chared without test during last three years;

(c) what are the exceptional cir. cums^ taces$_s$ such as epidemics prevailing at that time;

(d) what are the details of sera and vaccine tested during last three years;

(e) wnether it is a fact that certain importers are importing sub-standard vac-

cinea aa testing facilities are not available in the country; and

(f) if so, what steps are being taken in that direction?

THE MINISTER OF STATE IN THE DEPARTMENT OF HEALTH IN THE MINISTRY- OF HEALTH AND FAMILY WELFARE (KUMARI SAROJ KHAPARDE): (a) The sera and vaccine are special biological products and special provisions xegarding storage, packing, labelling and quality under the Drag$_s$ and Cosmetic Act and Rules are observed whi^ clearing the conignments.

(b) and (c) The vaccine released without test during the last 3 years are: —

(i) Measles Munips and Rubella **(MMR)** vaccine.

(ii) Hepatitis Vaccine.

(iii) Meningococcal vaccine.

The Hepatitis vaccine and Menin gococ-cal vaccine were released as special case because of the epidemics prevailing at the time of import.

(d) The details of the sample of Sera and Vaccine tested during the last 3 years are as follows;

	Tested	% Standard	Sub-Standard
1983-84	15	1	1*
1984-85	23	23	Nil
1985-86	19	19	Nil

*Oral Polio vaccine imported at Bombay which was substandard.

(e) and (f) Although facilities for testing of M. M. R. and Hepatitis vaccines are not available in the country, these are released ^only after checking the batch release certificate issued by the Health Authorities of the importing country.

Banking the drugs like iadomethacin

1494. SHRI RAJNI RANJAN SAHU: Will the Minister of HEALTH AND FAMILY WELFARE be pleased to. state:

(a) whether it is a fact that drugs like Indomethacin has been proved dangerous;

(b) whether it is also a fact that these drugs have been banned in number of countries;

(c) if so, name of the countries and the reasons in each case;

(d) whether it is a fact that these drugs are being marketed in our country despite the fact that number of substitute drugs are available; and

(e) if so, what are the reasons for not banning the same?

THE MINISTER OF STATE IN THE DEPARTMENT OF HEALTH IN THE MINISTRY OF HEALTH AND FAMILY WELFARE (KUMARI SAROJ KHAPARDE): (a) It is not a fact that Indomethacin as such has proved dangerous.

(b) and (c) So far as Government are aware only Controlled Release formulations of Indomethacin have been withdrawn by the manufacturers of the drugs in certain countries like West Germany, Argentina, Switzerland, Netherlands and Newzealand following reports of Gastro-intenstinal bleeding and perforation. No other products of Indomethacin is affected by this withdrawal.

- (d) and (e) Indomethacin and its substitute are being marketed in the country. However, the Controlled Release formulation of Indomethacin banned in some countries has not been approved for marketing in India and as such the question of banning it does not arise.